



**State of Louisiana**  
Department of Health and Hospitals  
Bureau of Health Services Financing

September 26, 2011

Dear Health Care Providers:

Preterm births are a serious problem in Louisiana. While the causes of preterm births are complex, hormone treatment with 17 hydroxyprogesterone caproate (17P) is effective in reducing the risk of repeat preterm births in certain women. Louisiana Medicaid has covered administration of 17P through its Professional Services Program since Sept. 1, 2010. When this coverage began, 17P was only available in a compounded version from pharmacies that specialized in compounding drugs.

In February 2011, the FDA approved a commercially-available 17P product, Makena, which is available at a cost many times that of the compounded version. In response to the manufacturer's pressure to stop individual pharmacy compounding, the FDA issued a statement on Makena on March 30, 2011. In the statement the FDA concluded:

"In order to support access to this important drug, at this time and under this unique situation, FDA does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate based on a valid prescription for an individually identified patient unless the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products."

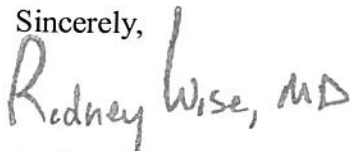
We have recently been notified of renewed efforts by the makers of Makena to pressure pharmacies in Louisiana to stop providing the compounded version of 17P. The Department of Health and Hospitals strongly supports the administration of 17P in women who have appropriate indications for its use and feels that the availability of compounded 17P is important as a treatment option. Ultimately, the decision of whether to prescribe compounded 17P or Makena is between the health care provider and the patient. Medicaid will continue to cover the reimbursement of 17P through its Professional Services Program using HCPCS code J3490-TH. The provider reimbursement using this code covers both the drug and its administration. Please understand that DHH fully supports the FDA decision to allow compounding to continue and encourages traditional compounding pharmacies to continue their efforts to provide safe compounded 17P.

September 26, 2011

Page 2

We encourage both providers and pharmacies to stay engaged in this process as we work to reduce Louisiana's high rate of preterm births. Part of that strategy is to ensure a continued supply of a safe and effective compounded option of 17P to Medicaid covered pregnant women, who account for approximately 70 percent of the births in the state annually. If you have additional concerns or questions about the use of 17P feel free to contact us.

Sincerely,

A handwritten signature in dark ink that reads "Rodney Wise, MD". The signature is written in a cursive, slightly slanted style.

Rodney Wise, M.D.  
Medicaid Medical Director